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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CHONG, KIMBERLY	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/805,075	JOHNSON ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to a method for identifying an agent for treating a diabetic or pre-diabetic individual comprising contacting a candidate agent with a kidney or pancreatic cell that expressed a nucleic acid encoding a polypeptide having SEQ ID No. 2 and determining the activity of the polypeptide and wherein the agent is an siRNA, classifiable in class 435, subclass 6.

II. Claims 1-7 and 9, drawn to a method for identifying an agent for treating a diabetic or pre-diabetic individual comprising contacting a candidate agent with a kidney or pancreatic cell that expressed a nucleic acid encoding a polypeptide having SEQ ID No. 2 and determining the activity of the polypeptide and wherein the agent is an antisense, classifiable in class 435, subclass 6.

III. Claims 1, 18-20 and 24-26, drawn to a method for identifying an agent for treating a diabetic or pre-diabetic individual comprising contacting a candidate agent with a kidney or pancreatic cell that expressed a nucleic acid encoding a polypeptide having SEQ ID No. 2 and determining the activity of the polypeptide and further comprising administering the agent to a diabetic or pre-diabetic animal, classifiable in class 435, subclass 6

IV. Claims 10-16, drawn to a method for identifying an agent for treating a diabetic or pre-diabetic individual comprising contacting a candidate agent with a kidney or pancreatic cell that expressed a nucleic acid encoding a polypeptide having SEQ ID No. 2 and determining the level of an RNA that encodes the polypeptide and wherein the agent is an siRNA, classifiable in class 435, subclass 6.

V. Claims 10-15 and 17, drawn to a method for identifying an agent for treating a diabetic or pre-diabetic individual comprising contacting a candidate agent with a kidney or pancreatic cell that expressed a nucleic acid encoding a polypeptide having SEQ ID No. 2 and determining the level of an RNA that encodes the polypeptide and wherein the agent is an antisense, classifiable in class 435, subclass 6.

VI. Claims 10, 18-20 and 24-26, drawn to a method for identifying an agent for treating a diabetic or pre-diabetic individual comprising contacting a candidate agent with a kidney or pancreatic cell that expressed a nucleic acid encoding a polypeptide having SEQ ID No. 2 and determining the level of an RNA that encodes said polypeptide and further comprising administering the agent to a diabetic or pre-diabetic animal, classifiable in class 435, subclass 6.

VII. Claims 21-23, drawn to a method for identifying an agent for treating a diabetic or pre-diabetic individual comprising contacting a candidate agent with polypeptide having glucose phosphorylating activity having at least 20

amino acids of SEQ ID No. 2 and determining the level of an RNA that encodes said polypeptide and wherein the agent is an siRNA, classifiable in class 435, subclass 6.

VIII. Claims 27-30, drawn to a method of introducing an expression cassette into pancreatic cell, classifiable in class 435, subclass 325 and 375.

IX. Claim 31, drawn to a method of diagnosing a prediabetic or diabetic patient, classifiable in class 435, subclass 6.

X. Claim 32, drawn to an isolated nucleic acid encoding a polypeptide comprising an amino acid sequence set forth in SEQ ID NO. 4, classifiable in class 536, subclass 24.5.

XI. Claim 33, drawn to an isolated nucleic acid encoding a polypeptide comprising an amino acid sequence set forth in SEQ ID NO. 3, classifiable in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are directed to related methods of identifying an agent for treating a diabetic or pre-diabetic individual. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the methods of identifying an agent are mutually exclusive, not obvious variants and have materially different modes of operation. For example, group I is drawn to contacting a siRNA with a kidney or

pancreatic cell and determining the activity of the polypeptide, group II is drawn to contacting an antisense agent with a kidney or pancreatic cell and determining the activity of the polypeptide and group III is drawn to contacting any agent with a kidney or pancreatic cell and determining the activity of the polypeptide and further comprising administering the agent to an animal and determining the response to glucose. Groups IV-VI are mutually exclusive, not obvious variants and have materially different modes of operation than groups I-III because they are drawn to a determining the level of an RNA that encodes the polypeptide, for example group IV involves contacting the kidney or pancreatic cell with an siRNA, group V involves contacting the kidney or pancreatic cell with an antisense agent and group VI involves contacting the kidney or pancreatic cell with any agent an further involves administering said agent to an animal and measuring glucose levels. Groups I-VI mutually exclusive, not obvious variants and have materially different modes of operation than group VII because groups VII involves contacting any candidate agent with a polypeptide have phosphorylating activity. Moreover, the methods of groups I-VI are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-VII and group VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In

the instant case, the different inventions are not disclosed as capable of use together and have different modes of operation. For example, the methods of groups I-VII involve contacting an agent with a kidney or pancreatic cell and determining the activity of said polypeptide which is materially different than group VIII drawn to a method of introducing an expression cassette into a pancreatic cell wherein when expressed inhibits the expression of a nucleic acid encoding a polypeptide. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-VII and group IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different modes of operation. For example, the methods of groups I-VII involve contacting an agent with a kidney or pancreatic cell and determining the activity of said polypeptide which is materially different than group IX drawn to a method of diagnosing a prediabetic or diabetic patient. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups I-VII and group X-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different modes of operation. For example, the methods of groups I-VII involve contacting an agent with a kidney or pancreatic cell and determining the activity of said polypeptide which is materially different than group X-XI drawn to an isolated nucleic acid sequences encoding a polypeptide having SEQ ID No. 4 and SEQ ID No. 3, respectively. Moreover, the inventions of groups X-XI are not disclosed as capable of use in the methods of groups I-VII. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of group VIII and group IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different modes of operation. For example, the method of groups VIII involve introducing an expression cassette into a pancreatic cell which is materially different than group IX drawn to a method of diagnosing a prediabetic or diabetic patient. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups VIII and group X-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different modes of operation. For example, the method of groups VIII involve introducing an expression cassette into a pancreatic cell which is materially different than group X-XI drawn to an isolated nucleic acid sequences encoding a polypeptide having SEQ ID No. 4 and SEQ ID No. 3, respectively. Moreover, the inventions of groups X-XI are not disclosed as capable of use in the method of group VIII. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions of groups IX and group X-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are not disclosed as capable of use together and have different modes of operation. For example, the method of group IX involves a method of diagnosing a prediabetic or diabetic patient which is materially different than group X-XI drawn to an isolated nucleic acid sequences encoding a polypeptide having SEQ ID No. 4 and SEQ ID No. 3, respectively. Moreover, the inventions of groups X-XI are not disclosed as capable of use in the methods of group IX. Furthermore restriction

is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Inventions X and XI are directed to related nucleic acids encoding a polypeptide. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, nucleic acid are mutually exclusive because each nucleic acid encodes an amino acid having a different sequence. For example, the nucleic acid of group X encodes an amino acid having SEQ ID NO. 4 and the nucleic acid of group XI encodes an amino acid having SEQ ID NO. 4. Moreover, nucleic acids of groups X and XI are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached at 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635

SEAN McGARRY
PRIMARY EXAMINER
1635